

REMARKS

The outstanding issues in the present matter are rejections of all claims under examination under 35 U.S.C. §§ 101 and 112, first paragraph (enablement). Office Action at pages 2-4. The following remarks are believed to overcome the rejections and to place the application in condition for allowance.

The Patent Office maintained the rejection of claims 1, 4-8, 10, 51-55, 70, and 72 under 35 U.S.C. § 101 for assertedly lacking either a specific and substantial utility or a well-established utility. (Office Action at page 2.) In maintaining the rejection, the Examiner acknowledged Applicants prior response of June 2, 2004 in which Applicants asserted that the claimed subject matter was patentably useful in diagnosing metastasized testicular cancer cells.

In the outstanding Office Action, however, the Examiner erred as a matter of law and as a matter of fact in asserting that "Applicants have to demonstrate that the secondary tumor was derived from the primary testicular cancer tumor cells." (Office Action at page 3.) In assessing patentable utility, the Examiner must accept Applicants' assertion of utility unless there is evidence to the contrary or a reasonable basis for doubting Applicants' assertion.

Langer and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true. (Citations omitted.) For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant.

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Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e., "question") the truth of the statement of utility. M.P.E.P. § 2107.02.

In the present case, the Examiner has not evaluated the logic of Applicants' statements and has not identified a reason to question the truth of the statement of utility. Rather, the Examiner has demanded that the disclosure satisfy a particular standard of

technical proof, i.e., that the application provide evidence of a testicular source for the cancer cells by showing that testicular cancer cells express the claim-recited nucleic acids at the preferential level of expression characteristic of healthy cells of the testis. For this reason, Applicants submit that the rejection of all examined claims under § 101 for an asserted lack of patentable utility is erroneous as a matter of law. Accordingly, the Examiner has failed to establish a *prima facie* case for a lack of patentable utility for the subject matter of any of the examined claims and the rejection should be withdrawn.

Applicants further submit that the Examiner erred as a matter of fact in effectively asserting that Applicants had failed to establish that a secondary tumor (i.e., metastasized cancer cells) arose from a primary tumor of testis cells. The instant application disclosed that the claim-recited nucleic acids were preferentially expressed in testis cells and provided data in support thereof (see, e.g., Example 3, page 112, lines 13-18, where agp-96614-a1 comprises SEQ ID NO:1). Detection of that preferential level of expression in a cell is diagnostic of a cell having a source in testis tissue. If such a cell is found in an area of the body other than the testis, the only scientifically reasonable basis for the presence of a testis cell in an abnormal location of a body is metastasis of a cancerous testis cell. Thus, detection of the preferential level of expression of the claim-recited nucleic acids, characteristic of testis cells, in a body location other than the testis, is diagnostic of metastasized testicular cancer cells. The Examiner has not provided any reason for questioning the position that the claim-recited nucleic acids would be expressed at the preferential level of expression in cells of the testis, whether healthy or cancerous. The Examiner has cited no evidence or scientific reasoning that provides a reasonable basis to doubt or question this assertion. For example, the Examiner has provided no evidence or reasoning to establish that one of ordinary skill in the art would expect the expression levels of the claim-recited nucleic acids to vary depending on whether or not the testis cell was cancerous. Thus, the Examiner has not met the burden of establishing that it is more likely than not that one of ordinary skill in the art would question the truth of the statement that the subject matter of the examined claims is useful in diagnosing metastasized testicular cancer cells. M.P.E.P. § 2107.02. Consequently, the Examiner's burden of establishing a *prima facie* case of lack of patentable utility has not been met.

For all of the foregoing reasons, Applicants submit that the Examiner has failed to establish a *prima facie* case of lack of patentable utility under 35 U.S.C. § 101 for any one of claims 1, 4-8, 10, 51-55, 70 or 72 and the rejection should be withdrawn.

The Examiner also rejected all claims under consideration for lack of enablement under 35 U.S.C. § 112, first paragraph. In support, the Examiner relied on the asserted lack of patentable utility and effectively asserted that one cannot teach how to use that which has no (patentable) use. As noted above, however, that premise is flawed. Applicants have established a patentable utility for the subject matter of each of the pending claims in methods for diagnosing metastasized testicular cancer cells. Because the rejection of all claims under consideration for an asserted lack of enablement was based solely on the Examiner's position that the claimed subject matter lacked patentable utility, and because that position was flawed, there is no proper basis for rejecting any of the claims under § 112, first paragraph, for an asserted lack of enablement. Accordingly, the rejection of claims 1, 4-8, 10, 51-55, 70, and 72 under § 112, first paragraph, for an asserted lack of enablement has been overcome and should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the outstanding rejections of claims 1, 4-8, 10, 51-55, 70 and 72 under 35 U.S.C. §§ 101 and 112, first paragraph (enablement), have been overcome. Accordingly, each of the pending claims is in condition for allowance and Applicants respectfully request early notification thereof.

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Respectfully submitted,

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